

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 829 271 A2

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

18.03.1998 Bulletin 1998/12

(51) Int Cl.⁶: **A61M 29/02, A61M 25/10**

(21) Application number: **97306752.3**

(22) Date of filing: **02.09.1997**

(84) Designated Contracting States:

**AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC
NL PT SE**

(30) Priority: **13.09.1996 US 713696**

(71) Applicant: **Angiorad L.L.C.**

Lake Charles, Louisiana 70605 (US)

(72) Inventor: **Liprie, Samuel F.**

Lake Charles, LA 70605 (US)

(74) Representative: **Woodward, John Calvin et al**

Venner Shipley & Co.

20 Little Britain

London EC1A 7DH (GB)

(54) **Dilatation/centering catheter**

(57) An apparatus for treating an occlusion or constriction, such as a stenosis in a blood vessel or other conduit in the body for treating a tumour or cancerous area occurring around a conduit or duct in the body. The apparatus comprises a catheter (10) provided with a catheter centering balloon (41) encircling a portion of

the catheter near its distal end. This centering balloon contains a plurality of thin spoke-like members (44,46,48,50). A second dilatation balloon (14) attached to the surface of the catheter is used to treat the stenosed area. A radioactive source of material (28) can be included for treating the stenosis or cancer.

EP 0 829 271 A2

BEST AVAILABLE COPY

Description

The present invention relates to a device for treating an occlusion or a constriction, such as a stenosis which would occur in various blood vessels and other bodily conduits as well as to the field of angioplasty. Additionally, the present invention is directed to a device for treating cancer which would occur in various body conduits or ducts, as well as to the field of brachytherapy.

Various techniques have been developed to treat many different conduits in the body when these conduits have become reduced in size due to the existence of a stenosis or have been completely occluded. These techniques include introducing a deflated balloon catheter to the site of an occlusion or constriction, such as a stenosis, inflating the balloon one or more times to eliminate the size of the stenosis, deflating the balloon and then removing the balloon catheter from the treatment site.

With respect to the vascular pathways, angioplasty is used to open an artery or blood vessel in the region where the stenosis or the occlusion has occurred. A typical angioplasty procedure consists of making a small incision through the body and into a blood vessel and then manoeuvring a guide wire through the vascular system to a point beyond the stenosis or occlusion. A hollow catheter with a deflatable balloon near its distal end is threaded over the guide wire and advanced to the point of stenosis or occlusion. The balloon is then inflated and deflated several times to widen the constricted area, and is then withdrawn from the body.

Unfortunately, although the angioplasty procedure does markedly reduce the area of stenosis or occlusion, many patients exhibit a reoccurrence of the stenosis within a few months of the original procedure.

Although the original stenosis occurs by means of the build up of plaque over a relatively long period of time, experimentation has lead many to believe that the reoccurrence of the stenosis after the original angioplasty procedure is unrelated to the cause of the original stenosis. It is believed that the inflation of the balloon catheter used in the angioplasty procedure or the placement of a stent in the area of the stenosis causes irritation to the blood vessel. This irritation produces a mechanism of action call hyperplasia, inducing the inner layer of the blood vessel cells to rapidly reproduce, thereby causing restenosis. It has been proposed that if the blood vessel is irradiated at the point of the stenosis with a radioactive dose, the mechanism that causes hyperplasia would be destroyed without harming the blood vessel itself.

During this procedure, it is important to precisely control the amount of radiation which is directed to the blood vessel wall, since too much radiation could actually induce hyperplasia as well as destroying a portion of the blood vessel, making it possible for an aneurism or rupture to occur. U.S. patent No.5,213,561, US patent

No.5,199,939 and PCT application PCT/US92/07447 describe various methods and apparatus for introducing radiation to the site of a stenosis to endeavour to prevent restenosis.

US patent No.5,213,561 describes a method and apparatus for preventing restenosis after angioplasty. A balloon catheter transported by a conventional guide wire is delivered to the location of the stenosis. Particles or crystals of radioactive material are embedded or mounted on a tube provided inside the balloon catheter. A retractable radiation shielding sleeve is slidable along the tube to cover the source of radioactive material. Upon completion of the angioplasty, the shielding sleeve is retracted and the area of the stenosis is irradiated. Although this apparatus does introduce radiation to the point of the stenosis, the retractable shielding surrounding the source of radioactive material makes this catheter bulky and unwieldy to use. In this regard, it is very doubtful that a catheter system this bulky would fit into the smaller branches or vessels of the heart. It is also doubtful that a catheter this bulky and stiff could be manoeuvred through the tighter bends and turns in many of the vessels.

US patent No. 5,213,561 illustrates a stent which is made of or coated with a radioactive material such as iridium 192. Since the radioactive material is provided on the outer surface of the stent, it is very difficult to precisely administer the proper dosage of radiation to prevent hyperplasia without administering a level of radiation which would actually induce hyperplasia or other deleterious effects to the blood vessel.

PCT application No.PCT/US92/07447 illustrates a method and apparatus for restenosis treatment by applying a radioactive dose to the stenosed region after reduction of the region by angioplasty or other means. As shown in Figure 4, an angioplasty balloon is expanded in the vicinity of a lesion site and radioactive elements provided on the exterior surface of the balloon are forced into contact with the region. Therefore, as with US patent No.5,213,561 the presence of the radioactive material on the exterior of the catheter would make it very difficult to apply the precise amount of radiation to the region of interest. Additionally, both the PCT application as well as US patent No.5,213,561 describe balloon catheters which do not allow the blood within the vessel to flow during inflation of the balloon.

Although there have been some attempts to construct a dilatation balloon allowing for some perfusion of bodily fluids during the inflation phase of the dilatation, the perfusion is greatly diminished by the overall size of the inflated balloon. Dilatation balloons must be able to hold a great amount of pressure (up to 16 atmospheres) and must also be able to inflate to large overall diameters to open the stenosis areas inside the bodily conduits or narrow tortuous passageways. Both of these requirements lead to large, bulky dilatation balloons that encompass most, if not all, of the area inside the stenosed vessel leading to large blockages of bodily fluids and

thus allowing for little, if any perfusion.

US patent Nos. 5,295,959 and 5,308,356 describe passive perfusion dilatation catheters having a series of non-longitudinal lobes. As particularly illustrated in Figure 1 of US patent No. 5,308,356 virtually the entire interior of the bodily conduit is blocked when the dilatation balloon is inflated, thereby preventing the flow of bodily fluids around the treatment site. Additionally, due to the particular structure of the balloons utilized, neither of the catheters disclosed in either of these US patents can be used to precisely centre the catheter within the bodily conduit at the site of treatment.

Attempts to utilize these types of dilatation balloons as a centering balloon or treating the patient with radioactive materials would greatly compromise the patient for the many minutes while the treatment is being implemented due to the diminished flow of bodily fluids or, in some cases, the complete blockage of bodily fluids. Any compromises to the dilatation balloon to achieve a greater flow rate would greatly decrease the effectiveness of the balloon on the stenosed area.

Therefore, there exists a need for a balloon catheter system that will achieve the greatest amount of dilatation possible and will also allow for the centering of the treatment lumen inside the bodily conduit or passageway while allowing for the maximum flow rate of bodily fluids around the treatment site.

US patent No. 5,199,939 shows a radioactive catheter for preventing restenosis after angioplasty. However, this patent merely indicates that an elongated flexible catheter is transported to the area of the original stenosis after a balloon catheter has been withdrawn, thereby lengthening the time to administer the entire procedure.

According to the invention, there is provided a treatment device comprising a flexible, elongated catheter having a distal end and a proximal end, said catheter including a first hollow treatment lumen extending within said catheter and having an exterior surface, a centering balloon attached to said exterior surface proximate to said distal end of said catheter characterised in that said centering balloon includes at least two inflatable spokes, said spokes encircling said distal end around a first particular point, wherein when inflated, said centering balloon permits perfusion of bodily fluids around said spokes.

In use, a radiopaque elongated, flexible guide wire is inserted into the body through a small incision and is then introduced into a blood vessel or similar conduit or passageway. Once in place, the catheter of the invention with its dilatation balloon (or series of balloons) and centering balloon (or series of balloons) thereon both attached near the distal end thereof is threaded over the guide wire and is also advanced to the location of treatment. The dilatation balloon or balloons is then inflated and deflated one or more times to reduce the size of the stenosis. At this point, the centering balloon or balloons would be inflated. Since the centering balloons inflate symmetrically and, in the preferred embodiment, are

long with thin widths, they serve only to centre the treatment lumen of the catheter inside the prior stenosed area while allowing for maximum bodily perfusion. A radioactive source or sources can then be advanced into position through the treatment lumen of the catheter to the site of the original stenosis. With the centering balloon or balloons inflated, the catheter and the radioactive source or sources are correctly centred within the bodily conduit or passageway to administer the precise dose to the original area of the stenosis. After a predetermined period of time has elapsed, the centering balloon or balloons are deflated and the radioactive source as well as the catheter and the guide wire are removed from the bodily conduit or passageway.

In another embodiment of the present invention, the catheter has a flexible membrane attached to either the dilatation balloon or the centering balloon to further ensure that blood will be able to flow through the perfusion channels through each of the lobes of a multi-lobed dilatation balloon thereby assuring that plaque or other material would not clog these channels.

Finally, if the catheter is used to transport a source of radiation to the treatment site without the necessity of reducing the size of a stenosis, the dilatation balloon need not be attached to the catheter. In this situation, the catheter would only include the centering balloon which would be inflated during the time the radiation source or sources are manoeuvred to the treatment site as well as during the treatment period. After a predetermined period of time, the centering balloon is deflated and the catheter, guide wire and radiation source are removed from the body.

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a longitudinal sectional view of a balloon catheter passing over a guide wire wherein the guide wire passes through a lumen inside the wall of the catheter;

Figure 2 is a longitudinal sectional view of a balloon catheter passing over a guide wire wherein the guide wire passes through an opening in the wall of the catheter and runs along the outside of the catheter;

Figure 3 is a cross sectional view of the catheter of Figure 1 showing the guide wire lumen and two inflation lumens inside the wall of the catheter and an inner treatment lumen of the catheter;

Figure 4 is a cross sectional view of the catheter of Figure 2 showing the guide wire on the outside of the catheter, two inflation lumens inside the wall of the catheter and an inner treatment lumen of the catheter;

Figure 5 is a transverse cross sectional view of an inflated multi-lobed dilatation balloon catheter;

Figure 6 is transverse cross sectional view of an inflated multi-lobed dilatation balloon catheter sur-

rounded by a flexible sheath member;
 Figure 7 is transverse cross sectional view of an inflated multi-lobed centering balloon catheter;
 Figure 8 is transverse cross sectional view of an inflated multi-lobed centering balloon catheter surrounded by a flexible sheath member;
 Figure 9 is a cross sectional view showing a three-lobe deflated centering balloon and a three-lobe deflated dilatation balloon each attached about the same area to a catheter;
 Figure 10 is a cross sectional view showing an inflated three-lobe centering balloon attached to a deflated dilatation balloon that is attached to a catheter;
 Figure 11 is a longitudinal view of a multi-lobe longitudinal centering balloon; and
 Figure 12 is a longitudinal view of a multi-lobe segmented centering balloon.

Although the present invention can be used to treat blockages, occlusion or constriction in many body conduits as well as narrow tortuous passageways, for ease of explanation, the present invention will be discussed with respect to a stenosis provided in a blood vessel. Additionally, also for ease of explanation, the same reference numeral will be used for like features.

Referring to Figure 1 and Figure 2, there is shown a catheter 10 of the present invention which comprises a flexible, elongated catheter 12 having a relatively large hollow treatment lumen 13 extending along the majority of the length of the catheter. An elongated, flexible guide wire 16 is used to ensure that the catheter 12 is manoeuvred to the proper location to treat the stenosis. In the embodiment shown in Figure 1, a guide wire lumen 22 is provided adjacent to one of the surfaces of the treatment lumen 13. The second embodiment shown in Figure 2 shows the guide wire 16 passing on the outside of catheter. The guide wire 16 enters the interior of the catheter by passing through an opening 19 provided at the termination of the distal end of the catheter. The guide wire then passes through slot 24 close to the distal end 15 of the catheter and runs along the outside surface of the treatment lumen 13. The distal end of the catheter end 15 is tapered at 18 to allow ease of manoeuvrability of the catheter through the narrow conduit or passageway.

The catheter according to the present invention can be used to reduce the size of any stenosis by inflating and deflating a dilatation balloon 14 affixed to the outside surface of the catheter. Radiopaque markings (not shown) are provided on the exterior surface of the catheter at approximately the beginning and the end of the location of the balloon or balloons. The present invention can also utilize one or more centering balloons, the purpose of which will be described hereinbelow. Furthermore, it should be noted that it would be possible to utilize this catheter with only the centering balloon or balloons and not employ the dilatation balloon 14 if the ste-

nosis is not reduced by inflating and deflating the dilatation balloon.

Once the catheter is manoeuvred to the treatment site, a radiation source or sources 28 can be manoeuvred through the treatment lumen 13 utilizing a guide type wire 30 containing the radiation source or sources. It should be noted that if a stenosis must be reduced, the dilatation balloon 14 would be inflated and deflated a number of times. Once the stenosis is reduced, the dilatation balloon is deflated completely and the centering balloon or balloons are inflated. At this point, the radiation source or sources 28 are manoeuvred to the treatment site utilizing the radiopaque markings. Various types of radiation sources known in the art could be utilized with this treatment. Typical of these radiation sources would be cesium 137, cobalt 60, iodine 125, iodine 131, cobalt 57, iridium 192, gold 198, palladium 103, strontium 89, strontium 90, phosphate 32 or yttrium 90. A solid plug 26 is provided in a distal end of a catheter at the point where the catheter begins to taper to ensure that the radiation source 28 remains within the interior of the catheter, and that contamination or germs provided within the treatment lumen 13 do not mix with bodily fluids provided within the passageway.

Figures 5-8 show a multi-lobed centering balloon as well as a multi-lobed dilatation balloon in various states of inflation or deflation. More specifically, Figure 5 shows the dilatation balloon 14 provided with its four lobes 36, 38, 40 and 42 in their inflated state. As shown in Figure 1 and Figure 2, this balloon is attached to the exterior surface of the catheter 12. Figure 5 also shows a multi-lobed centering balloon 41 having four lobes 44, 46, 48 and 50 in its deflated state. It should be noted that the exact number of lobes of both the dilatation balloon 14 and the centering balloon 41 are not crucial. For that matter, it is noted that the dilatation balloon 14 can be constructed without any lobes. In this situation, the inflation of the dilatation balloon 14 to reduce the size of the stenosis would thereby prevent the perfusion of bodily fluids during the time when this balloon is in its inflated state.

Figure 7 and Figure 8 show the dilatation balloon 14 in its deflated state, and the centering balloon 41 in its inflated state. As can be seen, the lobes 44, 46, 48 and 50 of the centering balloon 41 are relatively thin in volume and extend symmetrically from the surface of the catheter 12 as a plurality of radiating spokes or thin longitudinal lobes until they abut the inner surface of the passageway. When the dilatation balloon 14 is inflated, it fills approximately 90-100% of the passageway thus allowing for little, if any, bodily fluids to perfuse by. When the dilatation balloon 14 is deflated and the centering balloon 41 is inflated, only approximately 30-50% of the passageway is blocked, thus allowing for bodily fluids to easily perfuse by. Both the dilatation balloon 14 and the centering balloon 41 are manufactured from materials standard in the industry as is the guide wire 16 and the catheter 12.

Figure 6 and Figure 8 illustrate the utilization of a membrane or sheath 52 to achieve a greater dilatation affect while allowing for improved blood perfusion and centering of the treatment source. Since plaque or other bodily material can plug the perfusion channel or channels between adjacent lobes of the dilatation balloon 14, it is important that the channels between each of the lobes remain free of this material to allow bodily fluid, such as blood, to pass freely between these channels. This is especially true during an angioplasty procedure.

The present invention overcomes this problem by employing the membrane or sheath 52 which surrounds the entire ribbed balloon. This membrane or sheath 52 extends for either the entire length of the balloon 14 or for a portion of the length of the balloon 14. Once the balloon 14 is inflated, the membrane or sheath would be pulled tight between the gaps of the balloon lobes, as the lobes are inflated.

This particular configuration results in a greater dilatation affect since plaque or other bodily material cannot enter the gap spaces and is forced to move away from the membrane and lobes as expansion takes place due to the inflation of the balloon lobes. Additionally, a perfusion channel or channels is maintained open and bodily fluids will flow freely, since no bodily plaque material can enter the gap spaces to plug or create a damming affect.

The membrane can be constructed from a non-elastic or non-stretching type of material so that a thick overall diameter is achieved when the balloon lobes are inflated. Alternatively, the membrane can be constructed out of an elastic or stretching type of material so that when the balloon lobes are deflated, the membrane will recoil to its original shape and it is guaranteed that the balloon lobes will compress to as small of a diameter as possible around the catheter 12. This compression would allow for the balloon catheter when it is in its deflated state to pass through tiny constricted spaces. A stretchable membrane also allows for a thick diameter as long as the membrane cannot be stretched beyond the desired diameter of the inflated holes.

Alternatively, although not specifically illustrated in the drawings, it is to be noted that the membrane or sheath 52 need not surround the entire surface area of the lobes but can be provided merely between the lobes. Similar to the previously described embodiment, this membrane can be constructed from a non-elastic or an elastic material. Furthermore, this membrane portion may cover the entire length of the balloon 14 or only a portion of the length thereof.

Furthermore, the membrane or sheath 52 can be attached to either the dilatation balloon 14 or the centering balloon 41.

Referring back to Figure 1 and Figure 2 as well as Figure 3 and Figure 4, the dilatation balloon 14 can be inflated or deflated through the use of a balloon inflation port 56. A lumen 32 within the catheter 12 is connected to the balloon 14 and the port 56 is used for this purpose.

The centering balloon 41 can be inflated utilizing balloon inflation port 54. A lumen 34 provided within the catheter 12 connected to the balloon 41 and the port 54 is used for this purpose. Figure 3 is a partial cross sectional view of the catheter illustrated in Figure 1 but also shows the use of an internal lumen 22 for the guide wire 16. Figure 4 is a partial cross sectional view of the catheter shown in Figure 2 in which the guide wire 16 extends along a portion of the exterior surface of the catheter 12.

Figure 9 shows an embodiment in which a three-sided multi-lobed dilatation balloon 14 is provided along the majority of the surface of the catheter 12. Spaces between each of the lobes allow the various spokes 42 or lobes 41 of the centering balloon to pass therebetween. In this instance, the spokes 42 or lobes 41 of the centering balloon are attached directly to the exterior surface of the catheter 12.

Figure 10 shows an embodiment in which a non-lobed dilatation balloon 14 is attached to the exterior surface of the catheter 12. As illustrated in Figure 10, the balloon 14 is in its deflated state. The centering balloon 41 is shown in its inflated state in Figure 10 and is attached to the exterior surface of the non-lobed balloon 14.

Figure 11 shows a multi-lobe longitudinal centering balloon system which contains a plurality of centering balloons 41, which extend longitudinally along the surface of the catheter.

Figure 12 shows a multi-lobe segmented centering balloon system which contains a plurality of sets of centering balloons 42. This embodiment allows for the maximum perfusion possible.

Claims

1. A treatment device comprising a flexible, elongated catheter (10) having a distal end and a proximal end, said catheter including a first hollow treatment lumen (13) extending within said catheter and having an exterior surface, **characterised in that** a centering balloon (41) is attached to said exterior surface proximate to said distal end of said catheter said centering balloon including at least two inflatable members (44,46,48,50), encircling said distal end around a first particular point, wherein when inflated, said centering balloon permits perfusion of bodily fluids around said inflatable members.
2. The device as claimed in claim 1 characterised by a source of radiation (28) positioned within said hollow treatment lumen (13).
3. The device as claimed in claim 1 or claim 2 characterised by a flexible membrane (52) attached to said centering balloon (41), said flexible membrane being sized and configured to contact a body wall when said centering balloon is inflated.

4. The device as claimed in any preceding claim characterised in that said centering balloon (41) includes at least one additional set of inflatable members encircling a portion of said outer surface of said catheter (10), each of said additional sets of inflatable members encircling said outer surface at a point removed from said first particular point, each of said additional inflatable members of a particular set of additional inflatable members being symmetrically spaced from one another. 10
5. The device as claimed in any preceding claim characterised in that a second lumen (34) is provided within said catheter (10) connected to said centering balloon (41). 15
6. The device as claimed in any preceding claim characterised by a flexible, elongated guide wire (16) and a third lumen (22) provided within at least a portion of said catheter (10) within which said guide wire is positioned. 20
7. The device as claimed in any preceding claim characterised in that a seal (26) is positioned within said distal end of said catheter (10). 25
8. The device as claimed in any preceding claim characterised in that the distal end (18) is tapered.
9. The device as claimed in claim 2 characterised in that said source of radiation (28) is cesium 137, cobalt 60, iodine 125, iodine 131, cobalt 57, iridium 192, gold 198, palladium 103, strontium 89, strontium 90, phosphate 32 or yttrium 90. 30 35
10. The device as claimed in any preceding claim characterised in that a dilatation balloon (14) is attached to and encircles a portion of said distal end of said catheter. 40
11. The device as claimed in claim 10 characterised in that said dilatation balloon (14) is provided with a plurality of longitudinally extending lobes (36,38,40,42) whose distance from said exterior surface of said catheter (10) is relatively constant when said dilatation balloon is inflated. 45
12. The device as claimed in any preceding claim characterised in that the inflatable members are spokes. 50
13. A treatment device comprising a flexible, elongated catheter (10) having a distal end and a proximal end, said catheter having a first hollow treatment lumen (13) extending within said catheter and provided with an exterior surface characterised in that a centering balloon (41) is attached to said exterior surface proximate to the distal end (18) of the catheter (10), and said centering balloon includes at least two inflatable longitudinal balloons. 55
14. The device as claimed in claim 13 characterised in that said longitudinal balloons are equally spaced from one another around said exterior surface of said catheter.

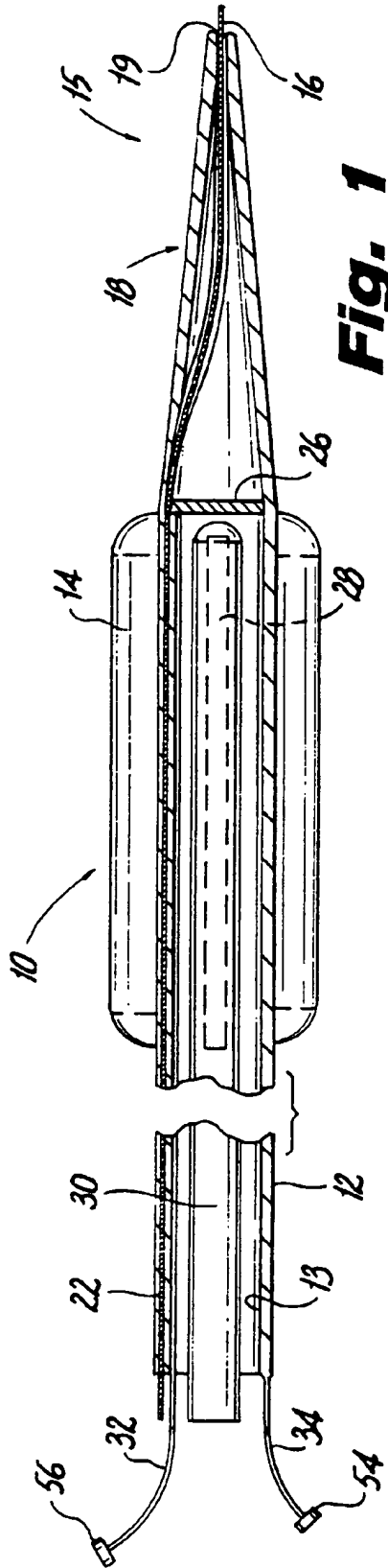


Fig. 1

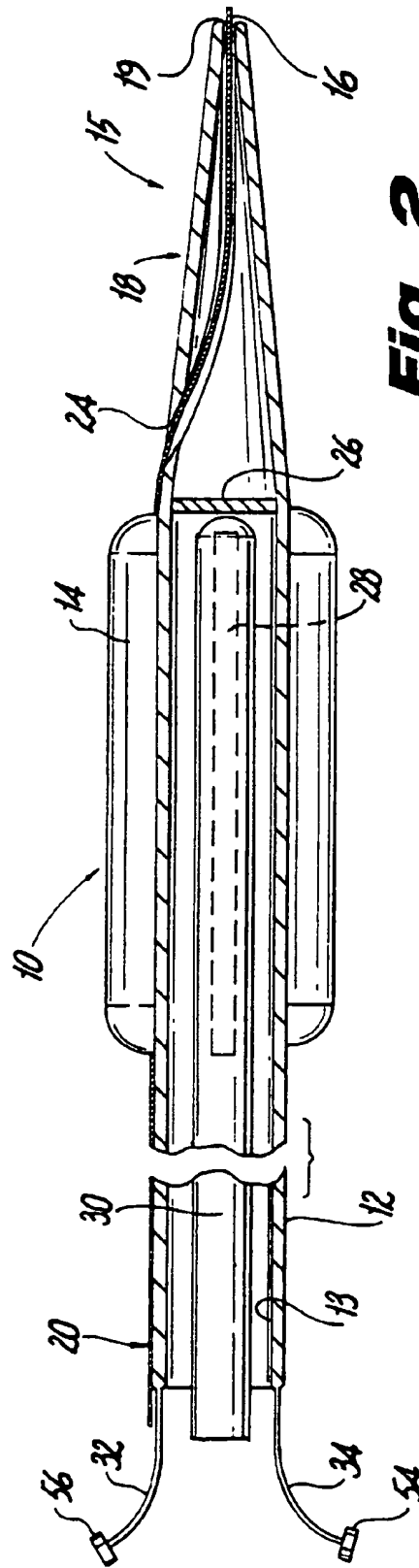


Fig. 2

BEST AVAILABLE COPY

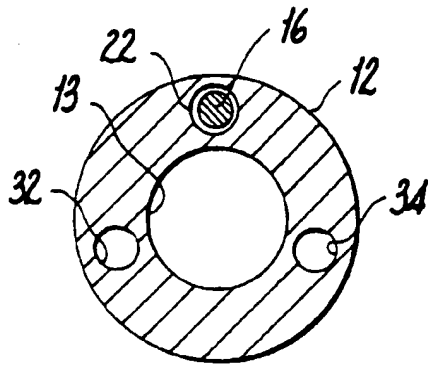


Fig. 3

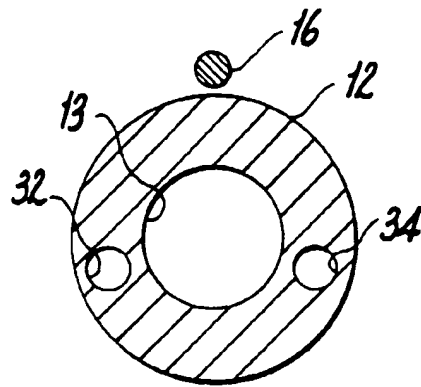


Fig. 4

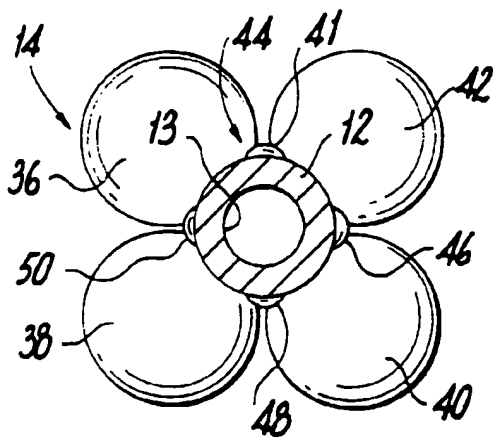


Fig. 5

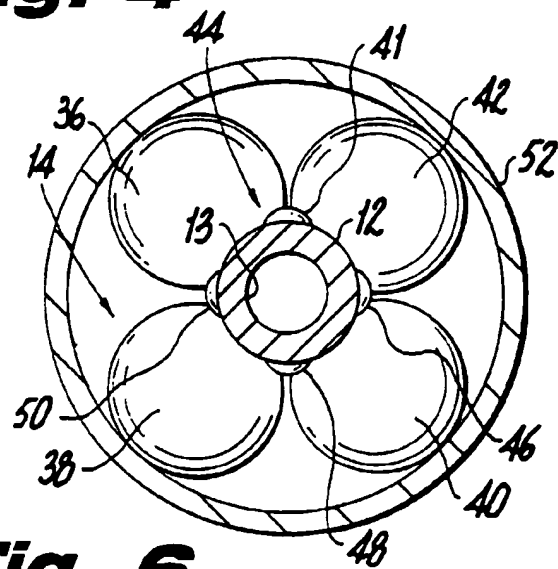


Fig. 6

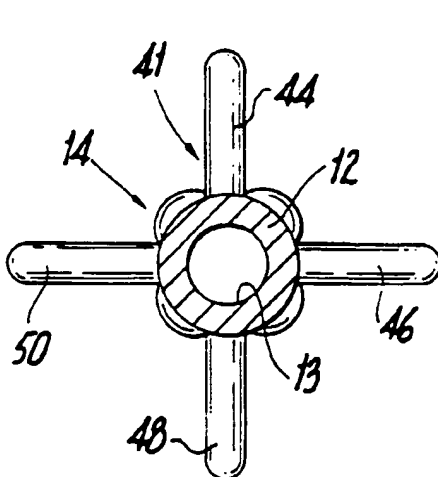


Fig. 7

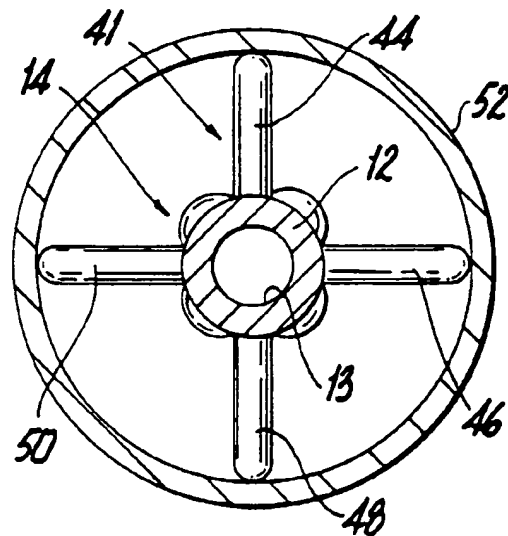


Fig. 8

BEST AVAILABLE COPY

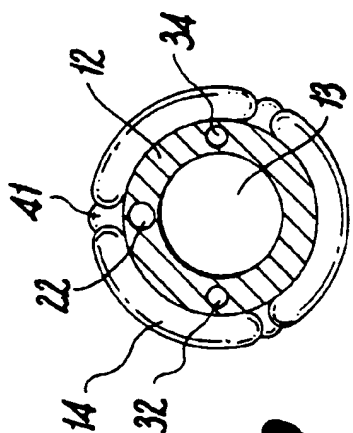


Fig. 9

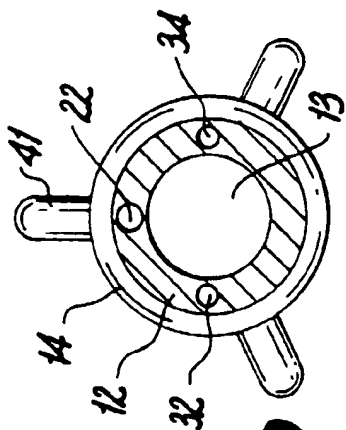


Fig. 10

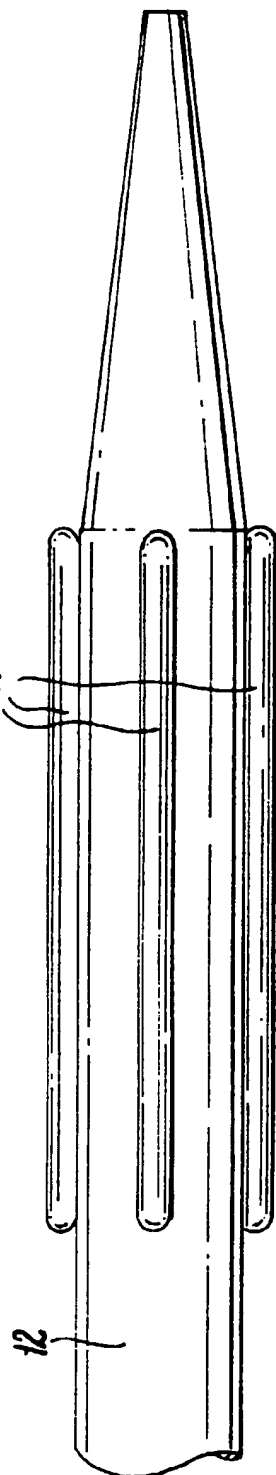


Fig. 11

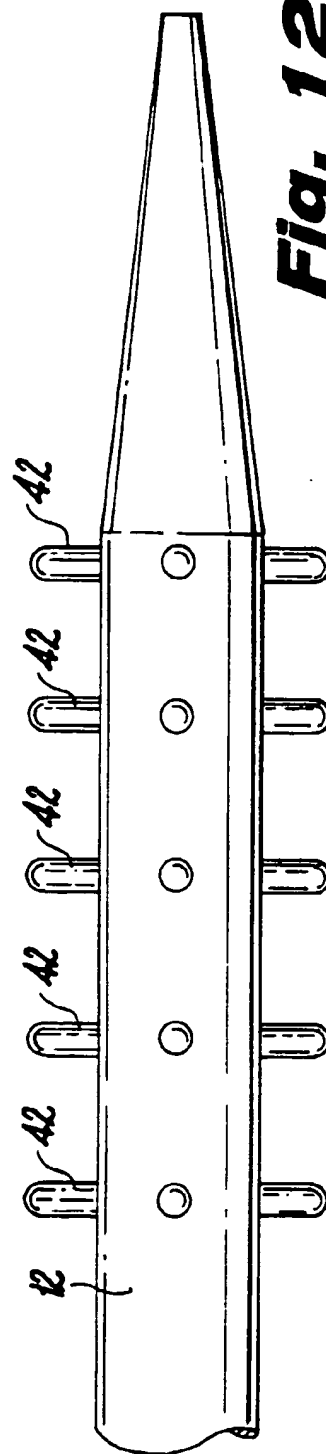


Fig. 12

REST AVAILABLE COPY